

JUN - 6 2003

K030332

Attachment E

510(k) Summary

Submitter Information:

Kent Hoffman
Chief Operating Officer
BioniCare Medical Technologies Inc.
47 R. Loveton Circle
Sparks, MD 21152
(410) 472-1888

Date Prepared:

January 30, 2003

Name and Classification of Device:

Transcutaneous electrical nerve stimulator for pain relief
Class II
Regulation – 21 CFR 882.5890
Product Code – 84GZJ

Device:

BioniCare® Stimulator, Model BIO-1000™

Predicate Device:

Bionicare® Stimulator, Model BIO-1000™

Device Description:

The BioniCare® Stimulator, Model BIO-1000™ consists of the electrodes, the lead wires, and the BioniCare® Stimulator. The stimulator is portable, battery operated and rechargeable. The lead wires connect the electrodes to the stimulator. These electrodes complete an electrical circuit allowing current flow. The stimulator produces a pulsed electrical signal through the lead wires and electrodes at the treatment site.

Statement of Intended Use:

The Bionicare® Stimulator, Model BIO-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation (clinical studies.)

Summary of Technological Characteristics of New device compared to Predicate Device:

The Bionicare® Model BIO-1000™ Version A, and the Bionicare® Model BIO-1000 Version B, systems generate the same electrical output. The analog circuit of Version A and the digital circuit of Version B produce the same frequency at $100 \pm 5\text{Hz}$, fixed.

The analog circuit of Version A and the analog circuit of Version B produce the same waveform as a monophasic spike shaped pulse.

The analog circuit of Version A and the digital circuit of Version B produce the same voltage output range which is 0-12 volts peak. Version A has a single channel of output and version B has two channels of output. The voltage pulse width, current output range, current pulse width, and maximum output change/channel are the same for Version A and Version B.

The output of Version A is displayed on red and green LEDs. The output on Version B is displayed on a LCD as numeric values in the range of the 0.0 to 12.0 volt output.

The twelve volt battery of Version A and the nine volt battery of Version B both produce the same output voltage over the range of 0.0 to 12.0 volts. Version A and Version B both comply with the standard ANSI/AAMI NS-4: 1988.)



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kent Hoffman
Chief Executive Officer
BioniCare Medical Technologies, Inc.
47 R Loveton Circle
Sparks, Maryland 21152

Re: K030332

Trade/Device Name: BioniCare® Stimulator Model BIO-1000™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: May 9, 2003
Received: May 9, 2003

Dear Mr. Hoffman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled; "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment C

Indications for Use Statement

Device Name

BioniCare® Stimulator, Model BIO-1000™

Indications for Use

The BioniCare® Stimulator, Model BIO-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation (clinical studies.)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K 030332

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:
(Per 21 CFR 801.109) ✓

OR Over-the-Counter Use _____

(Optional Format 1-2-96)